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| 10/821,732 | 04/08/2004 | Yasuyuki Kawashima | 11333/38 | 1524 |

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Chicago, IL 60610

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| EXAMINER |
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PETERSEN, CLARK D

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| ART UNIT | PAPER NUMBER |
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1657

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10/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/821,732

Applicant(s)

KAWASHIMA, YASUYUKI

Examiner

Clark D. Petersen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-21 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-21 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the Remarks filed by Applicant 9 August 2007.

Claims 11-21 and 25-27 are presented as originally filed, and claims 1-10 and 22-24 are cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Priority

In the Office Action mailed 9 February 2007 it was noted that Applicant had not provided reference to a foreign application in the specification, as required to gain priority benefit of that foreign application.

Applicant's amendment to the specification inserting reference to previously filed Japanese Patent Application No. 2003-106569 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-15, 17, 19, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al (US Patent # 6,165,740, issued 26 Dec 2000). Fukuda et al disclose a device capable of distinguishing between *Staphylococcus* and *Bacillus* bacteria in a sample by analyzing the sample by flow cytometry. Cultured *Staphylococcus* and *Bacillus* bacteria form different sized aggregates during growth. When analyzed by flow cytometry, the aggregates reflect fluorescent light and scatter other light differently, allowing a sensor to discern between the two types of bacteria (see Abstract; see Summary of the Invention, col. 3 line 61 to col. 4 line 48; see First Embodiment, col. 6 line 25 to col. 8 line 10, as examples). Additionally the unit is equipped with an analysis capability which can diagram particle distributions in two dimensions, from which any required information such as slope of distribution can be measured, reading on instant claims 12-14 (see Fig. 29, for example).

Therefore the teachings of Fukuda et al are deemed to anticipate the instant claims 11-15, 17, 19, and 25-27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-21 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al (US Patent # 6,165,740, issued 26 Dec 2000) in view of

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Kubitschek et al (J Bacteriol, Dec 1986) and in view of Chupp et al (US Pat # 5,631,165, issued 20 May 1997). The teachings of Fukuda et al are discussed above and applied as before.

Fukuda does not expressly teach a first detector that determines size information by detecting electrical resistance.

Fukuda does not expressly teach an output part for determining reliability of data, or that outputs a warning when the control unit has determined that identifying bacteria type is difficult.

Kubitschek et al teach that a Coulter-type impedance detector can reliably detect bacterial cell volume. They measure the size determined by impedance counter versus the size determined by pelleting cells and measuring the pellet volume versus cell count, and determine that the relationship between actual cell size and cell size determined by Coulter impedance counter is reliably the same (see p. 1466, col. 1, paragraph 1; see Fig. 1, p. 1467, for example). Kubitschek et al conclude "the agreement between mean cell volumes measured by the two methods provides evidence that cell volumes determined with the Coulter Counter-Analyzer system are in substantial agreement with the values determined biophysically for the same cells, thereby validating the use of electronic cell sizing for measurements of bacterial volumes" (see p. 1467, col. 2, final paragraph).

Chupp et al teach that a single instrument can comprise both an impedance transducer and a optical flowcell/transducer for detecting light scattering and fluorescence (see "System Overview", col. 11, lines 35-48, for example).

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Chupp et al also teach that a system can automatically determine statistical significance of the data it is collecting, and alter its actions based on its determination of statistical significance. For example, when cell counts are low, the apparatus can correct its counting time to improve statistical significance of the data. It would be obvious to include a warning system rather than alter counting times; both involve apparatus determination of statistical significance and determining a response to the determined significance (see col. 56, lines 25-27, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to arrange an apparatus comprising an optical cytometer and a Coulter impedance counter because Fukuda et al teach that cocci and bacilli can be differentiated by light scattering as well as determination of the volume of the aggregates they form as they grow, Kubitschek et al teach that a Coulter counter can reliably determine bacterial cell volume, and Chupp et al teach that one can combine a Coulter counter and an optical cytometer in a single apparatus.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to arrange a single apparatus for determining bacterial species by combining an impedance analyzer with an optical flow cytometer.

Response to arguments - 35 USC § 102

Applicant traverses the rejection of claims 11-15, 17, 19, and 25-27 under 35 U.S.C. 102(b) in the Office Action mailed 9 February 2007 as being anticipated by Fukuda et al (US Patent # 6,165,740, issued 26 Dec 2000).

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Applicants argue that Fukuda et al teach the identification of microorganisms based on two types of optical information obtained from scattered light, namely the intensity and the duration of the emitted scattered light. However, Applicant argues, Fukuda et al only teach the use of forward scattered light for determining bacterial type, not fluorescent light. Also, Applicant argues, the teachings of Fukuda et al do not anticipate the instant invention because Fukuda et al contains no teaching or suggestion of a control unit that creates a scattergram of bacteria using size and fluorescence information for determining bacterial type.

Applicant's arguments have been fully considered but are not deemed persuasive.

It is noted at the outset that Applicant has claimed an apparatus. Identical to the instantly claimed apparatus, the apparatus taught by Fukuda et al has the capability of detecting both fluorescent and forward scattered light from bacteria (see col. 6 lines 25-67, for example). Both types of light information are inputted into an analysis unit (see Fig. 1, for example). The control unit can use light information from both the light scattering and fluorescence detection to provide a two dimensional distribution of the data gathered from the bacteria; it is noted that Fukuda et al teach that both types of information are inputted into the analyzer to determine cell type (see Fig. 1, and col. 6 lines 25-67, for example). Furthermore the analysis unit can be used to create two dimensional diagrams that provide exactly the same information as the figures provided in the instant specification (see Figs. 9-14 of Fukuda; see Figs. 11-17 of the instant specification), in which bacterial types have a characteristic slope of their distribution.

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Therefore the instant apparatus, as claimed, is not patentably distinguishable from that taught by Fukuda et al.

Response to arguments - 35 USC § 103

Applicants traverse the rejection of claims 11-21 and 25-27 under 35 U.S.C. 103(a) in the Office Action mailed 9 February 2007 as being unpatentable over Fukuda et al (US Patent # 6,165,740, issued 26 Dec 2000) in view of Kubitschek et al (J Bacteriol, Dec 1986) and in view of Chupp et al (US Pat # 5,631,165, issued 20 May 1997).

Applicants argue that the rejection under 35 USC 103(a) fails for the same reasons as the rejection above under 35 USC 102(b), namely that Fukuda et al only teach the use of forward scattered light for determining bacterial type, not fluorescent light, and that the teachings of Fukuda et al do not anticipate the instant invention because Fukuda et al contains no teaching or suggestion of a control unit that creates a scattergram of bacteria using size and fluorescence information for determining bacterial type.

As discussed above, the teachings of Fukuda et al do, in fact, anticipate the invention as instantly claimed, and therefore the rejection under 35 USC 103(a) is also appropriate.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

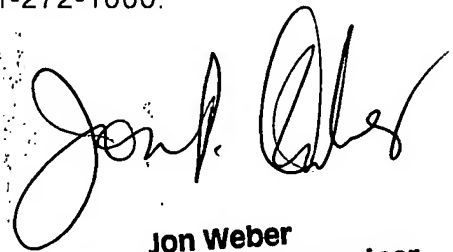
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
10/10/2007



Jon Weber
Supervisory Patent Examiner